

Remarks

Reconsideration and allowance of this application are respectfully requested.

This Response is being filed concurrently with a Request for Continued Examination ("RCE"). The RCE submission required under 37 CFR § 1.114 is Applicant's Amendment Under 37 CFR § 1.116 filed October 26, 2007. In response to the examiner's comments in the Advisory Action mailed November 20, 2007, please consider the following remarks in conjunction with the remarks presented in the Amendment.

In the Advisory Action the examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to perform the dialysis fluid-creating method of Mathieu in a bi-compartment bag, as taught by Rochat, in order to allow for dialysis fluid to be created by passing fluid through a single container."

Applicant respectfully disagrees. First, Rochat, Macabasco, and Mathieu would not have rendered obvious the claimed invention because their combined disclosures *do not teach all of Applicant's claim features*. Applicant's claimed bicompartiment bag includes "an assembly of two strong flexible outer sheets and a flexible inner sheet that divides an interior of the bag into a first chamber that is at least partially filled with a powdered solute." One of the two outer sheets has a first aperture located

therein and an *access bushing* disposed in the first aperture. The inner sheet has a second aperture located therein that is in communication with the bushing. And, to facilitate fluid flow to and from the bag, the bushing has "a first opening therein *that provides communication between a solvent inlet line and the first chamber*" and "a second opening therein *that provides communication between the second chamber and a solution discharge line.*" The combined disclosures of Rochat, Macabasco, and Mathieu fail to teach the aforementioned bushing feature, let alone a bushing that is configured for use with the claimed feature of the "first chamber that is at least partially filled with a powdered solute."

Second, for all of the reasons stated in Applicant's Amendment there would have been no incentive for the person having ordinary skill in the art to combine the references. Rochat is directed to a "*Blood Collecting and Filtering Apparatus.*" Macabasco is directed to a "Dockable Bag System and Method" and discloses that "[t]he present invention generally relates to the field of *blood bag* systems, and specifically relates to the field of sterile docking multiple *blood bag* systems" (column 1, lines 14-16) (emphasis added). Blood bags are used in *blood transfusion* technology, not in hemodialysis treatment.

The examiner's assertion that "in the blood bag system disclosed by Rochat, it is inherent that the layer of sodium bicarbonate would be located in the first chamber 13, before the

filtering layer 18 [sic, 12], in order to prevent particles from mixing into the blood" is not only illogical, but incorrect. During dialysis, the blood of a treated patient is circulated through the dialyser wherein the blood is separated from the dialysis fluid by a semipermeable membrane. In the remainder of the hemodialysis device there is *no contact* between the blood and any hemodialysis solution, in particular not in the bag in which the solution is prepared. Furthermore, it would make no sense at all to place any powdered solute into the blood bags of Rochat or Macabasco.

There simply would have been no incentive to combine the teachings of Rochat and Macabasco with that of Mathieu, which is directed to a "Flexible Medical Hemodialysis Packaging Unit for the Production of Concentrated Dialysis Solution Including a Device for the Same." The bag described by Mathieu is used for dry concentrates for the preparation of hemodialysis solution. As described by Mathieu, water is mixed with the powdered salt to produce a liquid concentrate. This concentrate is then further diluted in the device 40 and other concentrates may be added before it is supplied to a dialyser 46. See the depiction of "container 14" in Mathieu's Figure 1.

And as indicated above, even if the references were combined, the result would not be Applicant's presently claimed invention. Mathieu discloses a bag having a single simple fluid

port. See, e.g., Mathieu's Figure 2 depiction of "connecting hose 76" and the disclosure of "a flow connection through the connecting hose 76 to the cavity 82 of the bag" (column 9, lines 61-63). That is not Applicant's claimed bushing feature that has "a first opening therein *that provides communication between a solvent inlet line and the first chamber*" and "a second opening therein *that provides communication between the second chamber and a solution discharge line.*"


Accordingly, for at least these reasons, the combined disclosures of Rochat, Macabasco, and Mathieu would not have rendered obvious the presently claimed invention.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

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